

# **EXHIBIT 27**

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April 25, 2018

CONFIDENTIAL

Via Email (Alan.Slobodin@mail.house.gov) and U.S. Mail

Alan Slobodin, Esq.  
Chief Counsel for Oversight and Investigations  
United States House of Representatives  
Committee on Energy and Commerce  
2125 Rayburn House Office Building  
Washington, D.C. 20515-6115

Re: February 15, 2018 Letter to Cardinal Health, Inc.

Dear Alan:

On behalf of Cardinal Health, Inc., (“Cardinal Health” or “the company”) I am writing in response to the Committee’s questions raised in its February 15, 2018 letter. In addition to all of the information Cardinal Health has shared in prior correspondence with the Committee, the company shares the following information in response to Committee’s questions.

As you know, Cardinal Health is an integrated healthcare services company, delivering products and logistics support to healthcare providers worldwide. In its role as a wholesale pharmaceutical distributor, Cardinal Health provides a controlled distribution channel from manufacturers to licensed pharmacies and other healthcare providers, delivering a broad assortment of medications prescribed by doctors for treatment of their patients and other health care products. Cardinal Health does not practice medicine, diagnose medical conditions or needs, or write prescriptions; only licensed healthcare providers do. Cardinal Health’s mission and duty is to provide access to prescription medications for legitimate medical needs to pharmacies and healthcare providers appropriately licensed by the Drug Enforcement Administration (“DEA”) and state regulators, to ensure that prescribers and pharmacists have access to the medications they need when and where they need them to provide to patients.

Cardinal Health shares the Committee’s view that all players in the health care community have a responsibility to help prevent opioid abuse and diversion, and is committed to doing its part to help ensure opioids are not diverted from the distribution channels within which

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Cardinal Health operates. To this end, Cardinal Health has invested significant resources to develop and operate a rigorous anti-diversion system that employs sophisticated software and analysis as well as professional investigators to evaluate pharmacies, scrutinize customers and orders, and identify, block, and report orders that do not meet Cardinal Health's strict anti-diversion criteria. Every customer is subject to the anti-diversion process for every order. In addition, Cardinal Health reports all distributions of all oxycodone and hydrocodone to the DEA through DEA's ARCOS system on a monthly basis.

Cardinal Health's anti-diversion program has been continually improved to adapt to constantly evolving methods and tactics of diverters and a shifting regulatory landscape. Cardinal Health monitors available information to learn and adapt to these new challenges. Cardinal Health's dynamic anti-diversion system allows us to respond to emerging diversion schemes while continuing to ensure that patients get the medications they need from their healthcare providers.

1. *What was Cardinal Health's suspicious order threshold for hydrocodone dosage units per month for Family Discount Pharmacy in Mount Gay-Shamrock for each year between 2006 and 2012?*

Cardinal Health has identified data responsive to this request for the years 2008 to present. That information has been produced to the Committee at Bates number CAH\_HOUSE-001298. If additional data for years 2006 and 2007 is identified, Cardinal Health respectfully requests that it be allowed to supplement its production to the Committee.

Cardinal Health ceased distributing oxycodone and hydrocodone to Family Discount Pharmacy in Mount Gay-Shamrock in 2012. Family Discount Pharmacy has maintained an active and valid DEA registration and West Virginia BOP license since 2006.

- a. *Did these differ from the thresholds for other pharmacies in rural West Virginia? If so, by how much did they differ?*

Cardinal Health takes into account characteristics of each individual pharmacy customer in setting controlled substance distribution thresholds for that customer. These factors include the pharmacy's size, location, and business model, the pharmacy's historical volume of controlled substance purchasing, and its ratio of controlled substance purchasing to non-controlled substance purchasing. Because thresholds are set on a pharmacy-by-pharmacy basis based on the relevant context for each, comparing only thresholds across pharmacies in a "rural" area would not provide meaningful insight. Instead, other relevant factors would need to be considered such as average total prescriptions filled by the pharmacies and their ratios of purchases of controlled to non-controlled substances.

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In addition, Cardinal Health does not have information about any threshold levels that may have been set for pharmacies in West Virginia who are not Cardinal Health customers and cannot speak to the methodology used in setting them or how they might compare to Cardinal Health's thresholds.

*b. Please explain how Cardinal Health established the threshold order limit for Family Discount Pharmacy for each year between 2006 and 2012.*

Cardinal Health's methodology for setting customer thresholds has evolved over time. Standard Operating Procedures ("SOPs") describe in detail Cardinal Health's process for setting customer thresholds under its anti-diversion program. The first formal SOPs were developed in 2008. Cardinal Health's anti-diversion SOPs have been produced to the Committee at Bates numbers CAH\_HOUSE-000025 through CAH\_HOUSE-001296.

Before the implementation of the consolidated SOPs, Cardinal Health complied with its suspicious order monitoring obligations in at least two ways. First, Cardinal Health distribution center employees who worked in the secure cage and vault required by DEA for the storage and distribution of controlled substances were instructed to identify any orders that appeared excessive in relation to what other customers were buying and/or the customer's purchase history. Second, Cardinal Health submitted monthly Ingredient Limit Reports to DEA. The reports were generated based on a computer algorithm established by DEA, which was meant to be used to calculate the quantity which, if exceeded in one month, constituted an order which may be considered excessive or suspicious. Details concerning the algorithm can be found in the 1998 Report from the Suspicious Orders Task Force to the Attorney General at Appendix A, Exhibit II (produced to the Committee at Bates number CAH\_HOUSE-002207 through CAH\_HOUSE-002298). Documents relating to Cardinal Health's anti-diversion practices during this time period were produced to the Committee at Bates numbers CAH\_HOUSE-002197 through CAH\_HOUSE-002206.

*2. Did Cardinal Health use any analytic tools to assess whether the amount of pills distributed to Family Discount Pharmacy was appropriate for a town of 1,779 in a rural region of West Virginia? If so, what were they and what information did they yield about distribution to this pharmacy?*

Through its suspicious order monitoring system, Cardinal Health employs technology and analytics to evaluate its customers and identify suspicious ordering patterns. Cardinal Health worked with statisticians to develop and implement an analytic program for identifying potentially suspicious customers using data collected from previous customers to which Cardinal Health ceased distributing and reported as suspicious. This program was used prior to 2012 as a proactive tool for evaluating existing customer ordering patterns for indicia of diversion.

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Family Discount in Mount Gay-Shamrock is a large pharmacy that serves a surrounding county with a population of over 35,000. Family Discount has maintained an active and valid DEA registration and West Virginia BOP license since 2006. As a customer purchasing controlled substances from Cardinal Health, Family Discount was at all times subject to suspicious order monitoring and due diligence processes. Cardinal Health also deployed on-the-ground investigators who conducted multiple site visits to this pharmacy.

3. *Did Cardinal Health make any effort to determine the total number of pills sent to Mount Gay-Shamrock, and whether the amount of opioids that Cardinal Health sent to Family Discount Pharmacy was appropriate in light of this overall total?*

While volume is one factor that Cardinal Health considers in assessing a pharmacy's risk of diversion, Cardinal Health also weighs other important factors, such as the ratio of controlled to non-controlled substances ordered by the customer, the area in which the pharmacy is operating and demographics of the community, and the number of controlled substances shipped to a particular pharmacy in a particular period of time.

In addition, distribution information available to Cardinal Health generally is limited to its own data. For example, Cardinal Health does not have access to DEA ARCOS data, and would not have been able to determine the total volume of pills being sent to Mount Gay-Shamrock. In most cases, Cardinal Health only knows what it has distributed to a particular pharmacy and cannot see what other distributors have provided to any particular pharmacy or to pharmacies in a particular area.

4. *Cardinal Health's June 30th, 2017 response to the Committee noted its "Know Your Customer" program, which Cardinal Health indicated is a process by which it evaluates pharmacies and their use of controlled substances. Was Family Discount Pharmacy ever evaluated under the "Know Your Customer" component of Cardinal Health's anti-diversion program? If so, please provide all documents related to this evaluation. If not, why not?*

Family Discount Pharmacy was an existing customer at the time that Cardinal Health implemented the Know Your Customer account set up process. Family Discount Pharmacy was evaluated and monitored pursuant to Cardinal Health's anti-diversion system. This included conducting multiple on-the-ground site visits to investigate the customer and evaluate the potential risk of diversion, reviewing all orders that exceeded the customer's threshold, and requiring the customer to complete threshold event surveys to provide additional insight into the customer's legitimate ordering needs.

5. *Please provide all documents related to Cardinal Health's due diligence files for Family Discount Pharmacy, located in Mount Gay-Shamrock, West Virginia.*

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Documents responsive to this request have been produced to the Committee at Bates numbers CAH\_HOUSE-002300 through CAH\_HOUSE-002888 and CAH\_HOUSE-003314 through CAH\_HOUSE-003321.

6. *What was Cardinal Health's suspicious order threshold for hydrocodone dosage units per month for Hurley Drug Company for each year between 2006 and 2016?*

Cardinal Health has identified data responsive to this request for the years 2008 to present. That information has been produced to the Committee at Bates number CAH\_HOUSE-001298. If additional data for years 2006 and 2007 is identified, Cardinal Health respectfully requests that it be allowed to supplement its production to the Committee.

Cardinal Health ceased distributing oxycodone and hydrocodone to Hurley Drug Company in 2014. Hurley Drug Company has maintained an active and valid DEA registration and West Virginia BOP license since 2006.

- a. *Did these differ from the thresholds for other pharmacies in rural West Virginia? If so, by how much did they differ?*

Cardinal Health refers the Committee to the answer to Question 1(a) above.

- b. *Please explain how Cardinal Health established the threshold order limit for Hurley Drug Company for each year between 2006 and 2016.*

Cardinal Health refers the Committee to the answer to Question 1(b) above.

7. *How, if at all, did Cardinal Health account for the variances in distribution data to Hurley Drug Company between 2006 and 2016?*

While volume is one factor that Cardinal Health considers in assessing a pharmacy's risk of diversion, Cardinal Health also weighs other important factors, such as the ratio of controlled to non-controlled substances ordered by the customer, the area in which the pharmacy is operating and demographics of the community, and the number of controlled substances shipped to a particular pharmacy in a particular period of time.

Cardinal Health monitors all of its controlled substance distributions to pharmacies through Cardinal Health's suspicious order monitoring process. As part of that process, variations that resulted in threshold events resulted in the order being placed on hold. The order was filled only when Cardinal Health's anti-diversion personnel concluded that the order did not pose an unreasonable risk of diversion.

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Cardinal Health also reports distribution data to DEA through ARCOS. Cardinal Health does not ship opioids to customers that it believes present a substantial risk of diversion, and does not ship orders it determines are suspicious.

8. *Did Cardinal Health use any analytic tools to assess whether the amount of pills distributed to Hurley Drug Company was appropriate for a town of 3,191 in a rural region of West Virginia? If so, what were they and what information did they yield about distribution to this pharmacy? If no such tools were in use, why not?*

Through its suspicious order monitoring system, Cardinal Health employs technology and analytics to evaluate its customers and scrutinize individual orders to identify suspicious ordering patterns. Cardinal Health has worked with statisticians to develop and implement an analytic program for identifying potentially suspicious customers using data collected from previous customers who Cardinal Health had ceased distributing and reported as suspicious. This program was used prior to 2012 as a proactive tool for evaluating existing customer ordering patterns for indicia of diversion.

As a customer purchasing controlled substances from Cardinal Health, Hurley Drug Company was at all times subject to suspicious order monitoring and due diligence processes. Cardinal Health also deployed on-the-ground investigators who conducted multiple site visits to the pharmacy. Hurley Drug Company has maintained an active and valid DEA registration and West Virginia BOP license since 2006.

9. *Did Cardinal Health make any effort to determine the total number of pills sent to Williamson, and whether the amount of opioids that Cardinal Health sent to Hurley Drug Company was appropriate in light of this overall total?*

While volume is one factor that Cardinal Health considers in assessing a pharmacy's risk of diversion, Cardinal Health also weighs other important factors, such as the ratio of controlled to non-controlled substances ordered by the customer, the area in which the pharmacy is operating and demographics of the community, and the number of controlled substances shipped to a particular pharmacy in a particular period of time.

In addition, distribution information available to Cardinal Health generally is limited to its own data. For example, Cardinal Health does not have access to DEA ARCOS data, and would not have been able to determine the total volume of pills being sent to Williamson. In most cases, Cardinal Health only knows what it has distributed to a particular pharmacy and cannot see what other distributors have provided to any particular pharmacy or to pharmacies in a particular area.



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*10. Was Hurley Drug Company evaluated under the "Know Your Customer" component of Cardinal Health's anti-diversion program? If so, please provide all documents related to this evaluation. If not, why not?*

Hurley Drug Company was an existing customer at the time that Cardinal Health implemented the Know Your Customer account set up process. Hurley Drug Company was evaluated and monitored pursuant to Cardinal Health's anti-diversion system. This included conducting multiple on-the-ground site visits to investigate the customer and evaluate the potential risk of diversion, reviewing all orders that exceeded the customer's threshold, and requiring the customer to complete threshold event surveys to provide additional insight into the customer's legitimate ordering needs.

*11. Please provide all documents related to Cardinal Health's due diligence files for Hurley Drug Company, located in Williamson, West Virginia.*

Documents responsive to this request have been produced to the Committee at Bates numbers CAH\_HOUSE-003092 through CAH\_HOUSE-003321.

*12. What system did Cardinal Health have in place to monitor controlled substances purchases prior to 2008?*

Prior to 2008, Cardinal Health complied with its suspicious order monitoring obligations in at least two ways. First, Cardinal Health distribution center personnel working in the secure cage and vault required by DEA in connection with the distribution of controlled substances were instructed to identify any orders that appeared excessive in relation to what other customers were buying and/or the particular customer's purchase history. Second, Cardinal Health submitted monthly Ingredient Limit Reports to DEA. The reports were generated based on a computer algorithm established by DEA, which was meant to be used to calculate the quantity which, if exceeded in one month, constituted an order which may be considered excessive or suspicious. Details concerning the algorithm can be found in the 1998 Report from the Suspicious Orders Task Force to the Attorney General at Appendix A, Exhibit II (produced to the Committee at Bates numbers CAH\_HOUSE-002207 through CAH\_HOUSE-002298). Prior to 2007 at least, DEA did not require distributors to halt shipment of such orders, but rather only to report them to DEA, who had full visibility into distributions to all pharmacies, for any appropriate follow-up. Documents relating to Cardinal Health's policies and practices during this time period were produced to the Committee at Bates numbers CAH\_HOUSE-002197 through CAH\_HOUSE-002206.

Cardinal Health also conducted investigations of pharmacies believed to be engaged in internet sales, and cut off distributions of controlled substances to any pharmacies believed to present a significant risk of diversion.



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*13. Was your suspicious order monitoring program (or any predecessor program) in place in each year between 2006 and 2017?*

Yes. Cardinal Health's suspicious order monitoring system has been continuously enhanced and improved over time to address the ever-changing diversion landscape and to account for changing statements concerning regulatory expectations, provided via letters to industry and enforcement actions.

*a. Please provide any documents or manual outlining your suspicious order monitoring program for each of these years.*

Documents responsive to this request have been produced to the Committee at Bates numbers CAH\_HOUSE-000025 to CAH\_HOUSE-001296 and CAH\_HOUSE-002197 through CAH\_HOUSE-002206. If additional documents responsive to this request are identified, Cardinal Health respectfully requests that it be allowed to supplement its production to the Committee.

*b. If Cardinal Health's suspicious order monitoring program was not fully implemented in any year(s), please provide an explanation why.*

Not applicable based on response above.

*c. Please provide any other guidance provided to Cardinal Health employees or contractors related to suspicious order monitoring for each of these years.*

Cardinal Health refers the Committee to the answer to Question 13(a) above.

*14. Given the settlements described above, did Cardinal Health ever conduct an internal investigation or commission an external investigation related to its compliance with suspicious order monitoring requirements? If so, please provide copies of the report(s). If not, why not?*

Cardinal Health takes its regulatory obligations seriously, and has worked to continuously improve its controlled substance monitoring program over the years. Cardinal Health has hired outside consultants to help us improve the system, Cardinal has a committee of senior leaders who meet regularly to discuss those customers who order the largest volumes of controlled substances, and Cardinal Health conducts regular reviews of its program.

*15. Has Cardinal Health assessed the effectiveness of its suspicious order monitoring program for the years between 2006 and 2017? If so, please provide Cardinal Health's findings. If not, why not?*

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The methods through which pain medications are diverted from legitimate channels to illegitimate use are constantly changing. Cardinal Health has constantly enhanced and adapted its systems in response. When the provisions of the Controlled Substances Act regulating drug distributors were first enacted, the focus principally was on physical security within the supply chain. Later, distributors had to adopt their practices to identify risks of diversion first in connection with the proliferation of internet pharmacies, and later, pain management or “pill mill” clinics.

As part of Cardinal Health’s efforts to adapt and evolve along with ever-shifting methods of diversion, Cardinal Health’s anti-diversion team constantly assesses the effectiveness of the suspicious order monitoring program and has done so throughout the relevant time period.

*16. Did Cardinal Health receive the September 27, 2006 letter from DEA? If so, please describe what actions Cardinal Health took in response to this letter.*

Yes. Cardinal Health received the DEA’s letter and worked to ensure its systems complied with DEA’s new statements with respect to distributors’ duties with respect to suspicious order monitoring and reporting.

In 2006, Cardinal Health was already monitoring and reporting to DEA distributions of controlled substances that exceeded established limits or varied significantly from a standard ordering pattern. These limits and variances were identified based on an algorithm established by DEA. Cardinal Health’s distribution center employees were instructed to report orders that appeared excessive based on the type of customer and its prior ordering history. In addition, Cardinal Health had due diligence processes in place aimed at identifying and cutting off pharmacy customers that were engaging in diversion primarily through internet sales of controlled substances. This included in-person visits to pharmacies suspected of diversion.

*17. Did Cardinal Health receive the February 7, 2007 letter from DEA? If so, please describe what actions Cardinal Health took in response to this letter.*

Yes. Cardinal Health received the DEA’s letter and worked to ensure its systems complied with DEA’s new statements with respect to distributors’ duties with respect to suspicious order monitoring and reporting.

In 2007, Cardinal Health began requiring completion of a New Pharmacy Questionnaire as part of the account approval process for all new retail independent pharmacies. The questionnaire collected general information about the pharmacy, its owner, and the pharmacist in charge; general information about the pharmacy’s other suppliers; information about the pharmacy’s customers and their primary method of payment for controlled and non-controlled substances; and the pharmacy’s expected controlled substance ordering, among other

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information. Cardinal Health employees vetted these questionnaires, and conducted additional investigation where appropriate.

*18. Did Cardinal Health receive the December 27, 2007 letter from DEA? If so, please describe what actions Cardinal Health took in response to this letter.*

Yes. Cardinal Health received the DEA's letter and worked to ensure its systems complied with DEA's new statements with respect to distributors' duties with respect to suspicious order monitoring and reporting.

In 2008, Cardinal Health implemented an electronic order monitoring system. As part of this new system, Cardinal Health began establishing custom thresholds for controlled substance distribution for all customers based on the customer's size and class of trade, using historical controlled substance ordering data for all customers. The system was designed to alert analysts automatically whenever a customer's order volume exceeded its assigned threshold. All orders that triggered threshold events were held and reviewed to determine whether the order was justified or was suspicious. Orders that were determined to be suspicious were not shipped.

*19. Please provide all documents related to Cardinal Health's due diligence files for the following pharmacies: Family Discount Pharmacy, located in Stollings, West Virginia; and Tug Valley Pharmacy, located in Williamson, West Virginia.*

Documents responsive to this request have been produced to the Committee at Bates numbers CAH\_HOUSE-002889 through CAH\_HOUSE-003091 and CAH\_HOUSE-003314 through CAH\_HOUSE-003329

*20. Please provide a list of Cardinal Health's ten largest pharmacy customers in West Virginia, based upon hydrocodone and oxycodone dosage units, between 2006 and 2017.*

Information responsive to this request have been produced to the Committee at Bates number CAH\_HOUSE-001297.

*a. For each of those ten customers, please provide the total dosage units of hydrocodone and total dosage units of oxycodone that Cardinal Health distributed to each pharmacy each year from 2006 through 2017.*

Cardinal Health refers the Committee to the answer to Question 20 above.

*21. Please provide minutes from all Cardinal Health Board meetings held between 2006 and 2017.*

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Documents responsive to this request have been produced to the Committee at Bates numbers CAH\_HOUSE-001302 through CAH\_HOUSE-002196.

*22. Please provide minutes from all meetings of any subcommittee of the Cardinal Health Board of Directors, held between 2006 and 2017, where suspicious order monitoring or diversion of controlled substances was discussed.*

Cardinal Health refers the Committee to the answer to Question 21 above.

*23. Did Cardinal Health ever purchase market reports from IMS Health as part of the company's new customer due diligence? If so, in what years did Cardinal Health purchase IMS Health market reports and what specific types of reports did it purchase? If not, were market reports purchased from other sources? If Cardinal Health purchased third party reports or other data to use in its evaluation of existing and potential pharmacy customers from January 1, 2006 until present, please provide the third party vendor as well as the specific types of reports or data Cardinal Health utilized.*

Cardinal Health does not regularly purchase market reports from IMS Health. From time to time, Cardinal Health has purchased data from third party sources in connection with its pharmaceutical distribution business. For example, Cardinal Health purchases data from Symphony Health showing dispensing volumes from a large group of pharmacies nationwide, on a blinded basis.

*24. Cardinal Health's June 30, 2017 response referenced the "Know Your Customer" component of its anti-diversion program. When was this component formally established by the Company? When was it last revised? Did a similar anti-diversion component predate it? If so, please provide the differences between the current "Know Your Customer" component and its predecessor.*

In 2008, Cardinal Health issued formal SOPs governing the new account approval or "Know Your Customer" process for new retail independent and wholesale customers. Pursuant to the SOPs, which have been produced to the Committee, all potential customers are required to be evaluated through this process prior to the distribution of any controlled substances. The SOPs governing the new account approval process have been updated a number of times since 2008, most recently in 2017.

*25. Since January 1, 2006 has Cardinal Health received any customer orders from West Virginia for hydrocodone or oxycodone that exceeded either the dosage unit or strength thresholds set by Cardinal Health? If so, please provide details about these orders, and any action taken by the company, including but not limited to, whether the company decided to release the product for shipment.*

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Information responsive to this request has been produced to the Committee at Bates numbers CAH\_HOUSE-001299 through CAH\_HOUSE-001300.

*26. Cardinal Health's June 30, 2017 response to the Committee noted that it "stands by the appropriateness of its distributions in West Virginia" and asserted "based on average prescription sizes, Cardinal Health's distributions to West Virginia pharmacies were sufficient to allow each pharmacy to fill between 4.5 and 6.5 prescriptions for oxycodone and hydrocodone per day."*

*a. What year(s) does this average reference? Please provide documentation on how this average was calculated, and how (if at all) Cardinal Health used this average for purposes of monitoring for suspicious orders in West Virginia.*

The figures in Cardinal Health's June 30, 2017 response were calculated when preparing the response (that is, the figures were not derived from actual knowledge of prescriptions filled by specific customers). This was done to provide the Committee with an approximation of how many prescriptions were likely filled using the oxycodone and hydrocodone Cardinal Health distributed. The time period covered in the calculation was 2007 to 2012, the time period referenced in the 2016 news article from the *Charleston Gazette-Mail* cited by the Committee in its May 8, 2017 letter to Cardinal Health. The calculation used the total number of dosage units distributed, divided by the average number of pharmacy customers served, divided by the number of days over the time period, and then divided by an average prescription size of 60 pills.<sup>1</sup> These numbers were not used by Cardinal Health for purposes of monitoring for suspicious orders in West Virginia.

Cardinal Health's distributions of oxycodone and hydrocodone in West Virginia average 110,045 dosage units per day from 2007 until 2012. That is enough for 300 Cardinal Health customers to receive an average of 367 dosage units per day. Depending on the dosage units per prescription, Cardinal Health estimates that 367 dosage units of oxycodone and hydrocodone are sufficient to fill between 4.5 and 6.5 prescriptions. The number of pharmacies in West Virginia ordering from Cardinal Health fluctuated over those six years.

Based on these averages, for the entire six-year period referenced, Cardinal Health supplied the state of West Virginia with enough oxycodone and hydrocodone to treat less than 30,000 chronic pain patients in a state with a population of 1.8 million and an estimated 160,000 adults suffering with chronic pain. This calculation is based on reports from the Center for Disease Control and National Institute of Health indicating that 11.6% of adults suffer daily pain,

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<sup>1</sup> As was noted in the July 2017 letter, this is fewer pills than the actual national average prescription size using DEA and other publicly available information.

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and that adults suffering daily pain who are prescribed oxycodone or hydrocodone are likely to be prescribed at least 4 dosage units per day.

- b. DEA data provided to the Committee indicate that Cardinal Health shipped over 1.3 million hydrocodone pills to Family Discount Pharmacy each year from 2009 through 2011, which averages over 3,600 hydrocodone pills shipped to this pharmacy per day. How did Cardinal Health determine that its distribution of hydrocodone and oxycodone to Family Discount Pharmacy was appropriate given its stated average of between 4.5 and 6.5 prescriptions for oxycodone and hydrocodone to each pharmacy per day?*

For a description of Cardinal Health's methodology in setting thresholds for Family Discount Pharmacy, Cardinal Health refers the Committee to the answer to Question 1(b) above.

As described in the answer to Question 26(a), the 4.5 to 6.5 prescriptions was a calculation Cardinal Health performed in response to the Committee's May 8, 2017 request. As described, the calculation applied average figures in several regards to Cardinal Health's distribution data. Averages, by their nature, mean that some customers will be below and some above the figures provided. Cardinal Health refers the Committee to the response to Question 2 which indicates that Family Discount Pharmacy was and is a very large pharmacy ordering and dispensing a large volume of non-controlled substances. These numbers were not used by Cardinal Health for purposes of monitoring for suspicious orders in West Virginia.

- 27. Please provide copies of any dashboards and reports since January 1, 2006 of aggregated purchase data by West Virginia customers that Cardinal Health used to identify concerning trends in purchases potentially missed in the review of individual flagged orders.*

Cardinal Health's suspicious order monitoring system includes a dashboard of information about individual pharmacies available to employees involved in evaluating pharmacy orders. The content of the dashboard depends on what specific inquiries or information are selected, and draws from multiple separate continually updated sources of information. Thus, there is not a static "dashboard" or "report" concerning Cardinal Health customers in West Virginia, nor is there any dashboard reflecting aggregated West Virginia purchase data for production to the Committee.

- 28. According to its June 30, 2017 response to the Committee, Cardinal Health maintains that its "distributions of oxycodone and hydrocodone to West Virginia pharmacies were never in amounts that exceeded what was reasonably calculated to be necessary for pharmacies to meet the legitimate medical needs of patients." Prior to the Centers for Disease Control and Prevention issuing guidelines on opioid prescribing*



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*in March 2016, how did Cardinal Health determine the amounts of oxycodone and hydrocodone that were necessary for pharmacies to meet the legitimate medical needs of patients? Please provide documentation of how those determination were made, and how Cardinal Health used that information to ensure that its distributions never exceeded those amounts.*

Cardinal Health does not determine the amounts of oxycodone and hydrocodone—or any other pharmaceutical for that matter—that are necessary for legitimate patients. As a wholesale distributor, Cardinal Health does not practice medicine, diagnose medical conditions or needs, or write prescriptions; only licensed healthcare providers do.

The DEA determines the volume of opioids allowed to be legally manufactured every year in the United States in order to meet legitimate medical need. Each year, DEA assigns annual quotas for manufacturers' production of Schedule I and Schedule II controlled substances, including opioids, based on its assessment of the quantity of such drugs needed for legitimate medical use in the United States. However, Cardinal Health does use available information on national prescription averages in order to inform its understanding of what a customer's legitimate distribution needs may be in setting threshold limits for customers.

*29. Please provide any suspicious order reports that Cardinal Health submitted to the West Virginia Board of Pharmacy between 2006 and 2017.*

Cardinal Health has produced all documents and information responsive to this request that have been identified to date at Bates numbers CAH\_HOUSE-000024 and CAH\_HOUSE-002299. Cardinal Health has produced data beginning in 2012, which was the first year that suspicious order reporting was consolidated into one system. If additional data for prior years is identified, Cardinal Health respectfully requests that it be allowed to supplement its production to the Committee.

*30. Please provide any suspicious order reports that Cardinal Health submitted to DEA between 2006 and 2017.*

Cardinal Health has produced all documents and information responsive to this request that have been identified to date at Bates numbers CAH\_HOUSE-000024 and CAH\_HOUSE-002299. Cardinal Health has produced data beginning in 2012, which was the first year that suspicious order reporting was consolidated into one system. If additional data for prior years is identified, Cardinal Health respectfully requests that it be allowed to supplement its production to the Committee.

Prior to 2012, Cardinal Health reported to DEA concerning customers to whom it had ceased distribution of controlled substances based on concerns about potential diversion. From



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December 1, 2007 to February 2, 2012, Cardinal Health terminated or suspended shipment of controlled substances to approximately 330 customers nationwide.

*31. Please provide copies of all hydrocodone and oxycodone orders placed by West Virginia pharmacies between 2006 and 2017 that Cardinal Health refused to ship.*

Information responsive to this request has been produced to the Committee at Bates numbers CAH\_HOUSE-001299 through CAH\_HOUSE-001300.

*32. Please provide a list of all West Virginia pharmacies Cardinal Health terminated business relationships with since January 1, 2006, and the date of termination. Please describe the reason for the termination and provide copies of any documents or communication related to any pharmacy termination.*

Information responsive to this request has been produced to the Committee at Bates number CAH\_HOUSE-003330. In addition to this list, Cardinal Health has ceased distributing controlled substances to a number of additional pharmacies in West Virginia. Cardinal Health, however, cannot search for those pharmacies in a systematic way. For example, Cardinal Health ceased distributing oxycodone and hydrocodone to Family Discount Pharmacy of Mount Gay-Shamrock in 2012 and to Hurley Drug Company in 2014.

*33. Please provide a copy of any Cardinal Health written protocol regarding identification of suspicious orders reported by your company to DEA.*

Documents responsive to this request have been produced to the Committee at Bates numbers CAH\_HOUSE-000025 through CAH\_HOUSE-001296 and CAH\_HOUSE-002197 through CAH\_HOUSE-002206. If additional documents responsive to this request are identified, Cardinal Health respectfully requests that it be allowed to supplement its production to the Committee.

*34. For each year from 2006 to 2017, please provide the five states with the highest number of suspicious orders reported by your company to DEA.*

Cardinal Health has produced information from 2013 until 2017 that is responsive to this request at Bates number CAH\_HOUSE-001301. If additional data for earlier years is identified, Cardinal Health respectfully requests that it be allowed to supplement its production to the Committee.

*35. Since January 1, 2006, did Cardinal Health take any personnel actions for any reason related to the inadequate performance of DEA compliance responsibilities? If so, please provide the details of these personnel actions, including the name and*

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*position of the employee, date of the action, reason for the action, and all documents related to the personnel action.*

Cardinal Health takes its regulatory obligations seriously. Cardinal Health expects all personnel to follow established policies and procedures on all matters, including anti-diversion. Cardinal Health is proud of its anti-diversion professionals, who work day-in, day-out to provide a controlled distribution channel from manufacturers to licensed pharmacies and other healthcare providers, delivering a broad assortment of medications prescribed by doctors for treatment of their patients and other health care products. Over the years, Cardinal Health has changed personnel in its anti-diversion group (including changing the leadership of that organization in 2012) to ensure those with the best skill sets to meet the ever-evolving challenges are in place. Cardinal Health, however, does not have a database from which to pull a comprehensive list of personnel actions related to DEA compliance responsibilities.

\* \* \* \*

This letter contains proprietary business information and is marked confidential. Cardinal Health respectfully requests that such information be accorded special protection from disclosure and that it be maintained confidential under all applicable House and Committee rules. Additionally, this letter and Cardinal Health's productions to the Committee may contain material nonpublic information. Pursuant to the Stop Trading on Congressional Knowledge Act of 2012 ("STOCK Act"), Pub. L. 112-105, 126 Stat. 291, non-public information derived from a person's position as a Member of Congress or employee of Congress or gained from the performance of such person's official responsibilities may not be used as a means for making a private profit. Misuse of such information, including unauthorized disclosures to third parties outside of the Congress, may also give rise to liability under the securities laws, including section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder. *See also* House Comm. on Ethics, New Ethics Requirements Resulting from the STOCK Act (Apr. 4, 2012). Cardinal Health further requests that Committee staff provide the undersigned with notice and an opportunity to be heard in the event that the Committee determines that it will disclose any documents marked as confidential from Cardinal Health's production to a third party. Such treatment would be consistent with the respect for sensitive and proprietary business information the Committee has shown in the past.

Sincerely,

/s/ Enu Mainigi

Enu Mainigi